

Attorney Docket No.: 6809.230-US  
Filed: January 30, 2004  
Via Facsimile No.: 571-273-8300

Application Serial No.: 10/768,371  
Inventors: Igor Gonda et al.

## IN THE CLAIMS:

1-25 (Cancelled).

26. (New) A method of treating diabetes mellitus in a patient in need thereof, wherein the patient lacks the ability to maintain an acceptable blood glucose level without medical treatment, said method comprising:

- (a) supplying a predetermined amount of powdered insulin to a hand held device, said predetermined amount being in excess of that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said patient;
- (b) exhaling;
- (c) contacting said insulin with a compressed gas to form a cloud in said hand held device, said cloud comprising a repeatable amount of insulin, said repeatable amount being in excess of that amount required, in the bloodstream of said patient, to produce or maintain an acceptable serum glucose level in said patient, said cloud comprising insulin particles in the range between 0.25 and 6 microns; and
- (d) inhaling said cloud at an inspiratory flow rate in the range of 0.1 to 2.0 liters per second and wherein the inhaling of said cloud occurs with a total inhaled volume of 65% to 100% of lung capacity;
- (e) producing an acceptable blood glucose level in a patient who in the absence of steps a-d would not have an acceptable blood glucose level, wherein the acceptable glucose level is produced by systemically absorbing a controlled dose of insulin that comprises a percentage of the supplied amount of powdered insulin.

27.. (New) The method of claim 26, wherein the inhalation in the inhaling step is performed by making a maximal effort to inhale.

28. (New) The method of claim 26, wherein the aerosolization occurs with a compressed gas, having a pressure less than 400 psi.

29. (New) The method of claim 26 wherein the patient is a patient with type II diabetes.

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30. (New) The method of claim 26, further comprising repeating steps a-e, wherein in each repetition of steps a-e, the patient inhales substantially the same volume of air with the cloud of insulin.

31. (New) The method of claim 30, wherein the inhaling occurs at substantially the same flow rate.